

BD Launches Circulating Cell-Free DNA Blood Collection Tube for Cancer and Non-Invasive Prenatal Testing Applications

CE-IVD labeled PAXgene® Blood ccfDNA tube will be available in Western Europe

PR Newswire

FRANKLIN LAKES, N.J. and EYSINS, Switzerland, Feb. 20, 2018 [PRNewswire](#)/ -- BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced the commercial availability of the CE-IVD marked PAXgene® Blood ccfDNA tube within the European Economic Area and Switzerland (Western Europe). The plastic blood collection tube, which includes a proprietary sample stabilization additive and BD Vacutainer® Hemogard(TM) technology to help protect healthcare worker safety, was designed to ensure accurate and reproducible results in molecular diagnostic testing applications using circulating cell-free DNA (ccfDNA), such as cancer and non-invasive prenatal tests. The product was developed by PreAnalytiX GmbH, a joint venture between BD and QIAGEN.

Cells, including fetal cells, tumor cells, or cells from transplanted organs, release DNA into the blood stream. This DNA can be analyzed using PCR or next-generation sequencing to understand genetic characteristics of a developing fetus, a cancer tumor, or a transplanted organ from a blood draw. Molecular diagnostic tests using ccfDNA enable clinicians to gain actionable biological insights without a tissue biopsy or similar invasive test.

The PAXgene Blood ccfDNA tube provides a solution for clinical laboratories to stabilize samples when the sample cannot be processed on the same day it was collected. Where standard EDTA tubes require processing within hours before cells die and release genomic DNA into blood plasma (thus changing the native ccfDNA profile), the PAXgene tube has a unique stabilization chemistry that enables collection and processing to occur days apart, addressing a critical logistical hurdle for reference labs offering molecular testing outside of the hospital setting.

"Many molecular diagnostic companies, particularly in the cancer space, are developing new tests for monitoring and screening patients. They need a safe, clinically acceptable system for blood collection and ccfDNA processing that is capable of stabilizing a sample so that ccfDNA extraction can occur after the sample is transferred to another location, something that's not possible with EDTA tubes," said Frank Augello, general manager, PreAnalytiX GmbH. "This product will help molecular diagnostics companies in Western Europe offering ccfDNA based tests to grow their markets more quickly and ultimately help more patients access leading edge care."

"Reducing the potential for preanalytical errors is critical to ensuring the accuracy of molecular diagnostic tests," said Uwe Oelmueller, Ph.D., vice president, head of MDx development sample technologies for QIAGEN, GmbH. "We are confident that the CE-IVD marked version of the PAXgene Blood ccfDNA tube will provide robust safety, and reliable and reproducible ccfDNA-based test results, helping to expand access to molecular diagnostic testing in Western Europe."

Since 2016, PreAnalytiX has marketed a research use only (RUO) version of the PAXgene Blood ccfDNA tube together with the QIAasymphony® PAXgene® Blood ccfDNA kit as a fully integrated and standardized system covering all preanalytical workflow steps from blood collection, stabilization, transport, storage and isolation of high quality ccfDNA. The RUO tube version has the same format and stabilization chemistry as the new CE-marked version. The RUO version of the tube will be discontinued as customers adopt the CE-IVD. For more information, visit <https://www.preanalytix.com/products/blood/ccfDNA/paxgene-blood-ccfdna-tube-ivd-use>.

About PreAnalytiX

PreAnalytiX, a joint venture between BD and QIAGEN, develops, manufactures and sells integrated and standardized systems for sample collection, stabilization and purification of high-quality RNA, microRNA and DNA from human blood, bone marrow, or tissue specimens. The company serves healthcare institutions, academic researchers, clinical laboratories and the pharmaceutical industry with a broad array of manual and automated products.

About BD

BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. The company supports the heroes on the frontlines of health care by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its 65,000 employees have a passion and commitment to help improve patient outcomes, improve the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to better diagnose

disease and advance researchers' capabilities to develop the next generation of diagnostics and therapeutics. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to health care. In 2017, BD welcomed C. R. Bard and its products into the BD family. For more information on BD, please visit bd.com.

About QIAGEN

QIAGEN N.V., a Netherlands-based holding company, is the leading global provider of Sample to Insight solutions that enable customers to gain valuable molecular insights from samples containing the building blocks of life. Our sample technologies isolate and process DNA, RNA and proteins from blood, tissue and other materials. Assay technologies make these biomolecules visible and ready for analysis. Bioinformatics software and knowledge bases interpret data to report relevant, actionable insights. Automation solutions tie these together in seamless and cost-effective workflows. QIAGEN provides solutions to more than 500,000 customers around the world in Molecular Diagnostics (human healthcare), Applied Testing (forensics, veterinary testing and food safety), Pharma (pharma and biotech companies) and Academia (life sciences research). As of September 30, 2017, QIAGEN employed approximately 4,600 people in over 35 locations worldwide. Further information can be found at <http://www.qiagen.com>.

Forward Looking Statements

This press release contains certain forward-looking statements (as defined under Federal securities laws) regarding PAXgene Blood ccfDNA tube. Forward looking statements may be identified by use of words such as "will", "intend", "plan", "believe", "expect" or other words of similar meaning. All such statements are based upon the current expectations of BD and involve a number of business risks and uncertainties that could cause actual results to differ materially from anticipated results described, implied or projected in any forward-looking statement, including, without limitation, regulatory changes, competition, rapid or unexpected changes in technologies, and the ability to gain market. We do not intend to update any forward-looking statements to reflect events or circumstances after the date hereof except as required by applicable laws or regulations.

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